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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,693	02/15/2005	Camille Georges Wermuth	WERM 3001	8393

23364 7590 11/21/2007

BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

MAIL DATE	DELIVERY MODE
11/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,693	WERMUTH, CAMILLE GEORGES	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-13 and 25-33* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a 371 of PCT/IB03/03698.

Claims 14-24 (preliminary amendments canceled 16-24, typo-correction) have been canceled. Claims 1-13, 25-33 are pending.

2. Claims 1, 6-7, 9, 12-13, 25, 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompassed the scope of "solvates/hydrates of the compounds" for which no description or enabling support can be found in the specification. Unlike formation of salts between a pharmaceutically acceptable acid and an organic base compound of the claims, the formation of "solvates" or "hydrates" must find descriptive and enabling support for such claimed scope (see Braga et al. p.3640 right column). A survey of the specification indicated there is no description of which solvent can form solvate with the compounds, under what condition will such solvates be obtained, and whether the solvates will have consistent properties to be considered inclusive as being a "Markush" alternative of the compounds.

No examples, no process of making, no starting material or operability can be found for any compound encompassed by the Markush formula to have the ability in forming what solvate/hydrate. Therefore, absent of description and enabling disclosure, the specification is insufficient in supporting the "claimed" scope of "solvates of the compounds".

3. Claims 7-8, 12, 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is confusing as to what is the quantitative relationship of the active ingredients and the carrier in claim 7 because claim 7 has no quantitative limitation. Please note that a "pharmaceutical" composition can neither be ineffective nor be toxic. A claim to a pharmaceutical composition without a quantitative limitation such as *therapeutic effective amount* etc. is self conflicting.

It is also self conflicting for the method claim 25 wherein the method is for "prophylaxis" of a patient. Please note that once a person is diagnosed with disease i.e. a patient, no long can de novo prophylaxis occur. Whatever maintenance dose being administered to a "patient" in preventing future pathology or symptoms is encompassed by the term "treatment" of a patient. Therefore, it is recommended that the term "prophylaxis" be deleted.

The intended use terms such as "for use in treatment", "for prophylaxis of" or "by therapy or diagnosis practiced" are no limiting but created confusion as to what is the quantity being in the composition or being used in a method. It is recommended that the terms be replaced with a proper quantitative limitation such as anti-depression effective amount, treating anxiety effective amount etc.

4. Claims 12-13 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 4-5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The "intended" use of claims 11-12 are not limiting. Therefore, to the extend that claims 12-13 are the same salts of claims 1, 4-5, they are essential duplicates. One set of duplicate claims should be canceled.

5. Claims 25-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It is noted that there is no definition in the art recognizing the term "stress-related affective disorder" (see Sheline et al. Tsuji et al. Minner et al. or Braga et al.) While the art recognized that "affective disorder" is a psychiatric disorder marked by identifiable symptoms (see Answers.com) and stress or chronic stress may develop affective disorders, "stress-related affective disorder" has not been recognized as a clinical condition.

The specification defines the term "stress-induced affective disorder" being used herein to include any disorder associated with elevated levels of 5-HT (5-hydroxytryptamine; serotonin) resultant from newly synthesized 5-HT which is incredible, including even the disorder that has not yet been correlated but continuously being developed in the field of 5HT research. Further, while affective disorder is defined with clinical symptoms, no nexus exclusively to 5HT being the sole neurotransmitter was described in the state of the art (see Miner et al. or Braga et al.).

Therefore, the specification provided insufficient description as to what constitutes "stress-related affective disorder" or the scope and meets and bounds for the claims containing the term.

6. Claims 7-13, 25-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a scope of enablement rejection.

The specification disclosed that the claimed pamoate salts depend entirely on the active free base for its therapeutic activity. The free base or its acid additions salts are known in the art for therapeutic treatment of depression, anxiety, migraine or sleep apnoea (see US 4,835,151, US 4,461,771). No nexus was found in the record that the pamoate salts can have activity beyond the basic drug as to be able to treat such diversity of disorders of claim 26 or the unspecific scope of claim 25 or formulating a dosage composition containing such salts.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-9,11-13,25-31, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gittos et al. US 4,835,151 or US 4,461,771 supplemented with RN 103353-87-3 in view of Berge et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

Gittos et al. '151 (see col. 8, lines 5-48) or '771 (see col. 2-3 compounds and col. 5 lines 39-54 addition salts of the compounds) generically disclosed pharmaceutically acceptable acid addition salts of the instant formula I.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the particular pamoate salt was not named or exemplified. Berge et al. taught that pharmaceutical acid addition salts are well known to have advantages properties (see whole article) and some are even acceptable by the FDA (see p.2)

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art is well aware of that not all acid addition salts of a given compound have identical activity. Variations among the different salts of acid addition compounds are well within the expectation in preparing salts as modifier of a pharmaceutical compound. One having ordinary skill in the art in possession of all the claimed compounds being disclosed by US 4,835,151 or US 4,461,771 and their generically disclosed *pharmaceutically acceptable* acid addition salts would be motivated to pick and choose the pamoate simply because it is a FDA acceptable form. In absence of unexpected results, there is nothing unobvious in picking some among the many salts generically disclosed.

The specification disclosed that the hydrochloride salt of AGN-2979 (RN 103353-87-3) is known to have toxicity in inducing weight loss in patient (p. 2), no record supports that all of the hydrochloride salts of formula I share this same toxicity. Nor was there any evidence to support that pamoate of all the compounds of formula I have unexpected results of non-toxic in inducing weight loss. While AGN-2979 pamoate showing unexpected nontoxic property thus would be unobvious over the art, the other compounds of formula I have not been supported by such unexpectancy.

8. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 14, 2007

Celia Chang
Primary Examiner
Art Unit 1625